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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,003	MA ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

    1. Claims 8-13, drawn to chimeric protein comprising an FTL3 ligand comprising SEQ ID NO:2 or portions thereof and a tumoricidal agent, classified in class 514, subclass 2 or class 530, subclass 387.3.

    2. Claims 8-17, drawn to chimeric protein comprising an FTL3 ligand comprising SEQ ID NO:2 or portions thereof and a tumoricidal agent comprising an antibody, classified in class 514, subclass 2 or class 530, subclass 387.3.

    3. Claims 8-13 and 18 in part, drawn to chimeric protein comprising an FTL3 ligand comprising SEQ ID NO:2 or portions thereof and a tumoricidal agent comprising Fas ligand or biologically active extracellular domain thereof, classified in class 514, subclass 2 or class 530, subclass 387.3.

    4. Claims 8-13 and 18 in part, drawn to chimeric protein comprising an FTL3 ligand comprising SEQ ID NO:2 or portions thereof and a tumoricidal agent comprising TNF or biologically active extracellular domain thereof, classified in class 514, subclass 2 or class 530, subclass 387.3.

    5. Claims 8-13 and 18 in part, drawn to chimeric protein comprising an FTL3 ligand comprising SEQ ID NO:2 or portions thereof and a tumoricidal agent comprising TRAIL or biologically active extracellular domain thereof, classified in class 514, subclass 2 or class 530, subclass 387.3.

6. Claims 8-13, 21 and 22, drawn to chimeric protein comprising an FTL3 ligand comprising SEQ ID NO:2 or portions thereof, a linking peptide and a tumoricidal agent , classified in class 514, subclass 2 or class 530, subclass 387.3.

7. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO: 24 (HuSMVH/Fc/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

8. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO: 26 (HuSMVH/Fc/Link/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

9. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO: 28 (FL/Fc/huSMFv), classified in class 514, subclass 2 or class 530, subclass 387.3.

10. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:30 (chSMVH/Fc/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

11. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:32 (chSMVH/Fc/Link/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

12. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:34 (FL/Fc/chSMFv), classified in class 514, subclass 2 or class 530, subclass 387.3.

13. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:44 (CD20VH/Fc/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

14. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:46 (CD20VIH/Fc/Link/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

15. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:48 (FL/Fc/CD20Fv), classified in class 514, subclass 2 or class 530, subclass 387.3.

16. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:58 (her2VH/Fc/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

17. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:60 (her2VH/Fc/Link/FL), classified in class 514, subclass 2 or class 530, subclass 387.3.

18. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:62 (FL/Fc/her2Fv), classified in class 514, subclass 2 or class 530, subclass 387.3.

19. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:64 (hFLex/Trailex), classified in class 514, subclass 2 or class 530, subclass 387.3.

20. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:66 (hFLex/IZ/Trailex), classified in class 514, subclass 2 or class 530, subclass 387.3.

21. Claim 23 in part, drawn to a chimeric protein of SEQ ID NO:68 (hFLex/Fc/Trailex), classified in class 514, subclass 2 or class 530, subclass 387.3.

22. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 23 (encoding HuSMVH/Fc/FL), classified in class 536, subclass 23.4.

23. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 25 (encoding HuSMVH/Fc/Link/FL), classified in class 536, subclass 23.4.

24. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 27 (encoding FL/Fc/huSMFv), classified in class 536, subclass 23.4.

25. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 29 (encoding FL/Fc/huSMFv), classified in class 536, subclass 23.4.

26. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 31 (encoding chSMVH/Fc/FL), classified in class 536, subclass 23.4.

27. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 33 (encoding chSMVH/Fc/Link/FL), classified in class 536, subclass 23.4.

28. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 43 (encoding CD20VH/Fc/FL), classified in class 536, subclass 23.4.

29. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 45 (encoding CD20VIH/Fc/Link/FL), classified in class 536, subclass 23.4.

30. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 47 (encoding FL/Fc/CD20Fv), classified in class 536, subclass 23.4.

31. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric

proteins with vector transfected cells of SEQ ID NO: 57 (encoding her2VH/Fc/FL), classified in class 536, subclass 23.4.

32. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 59 (encoding her2VH/Fc/Link/FL), classified in class 536, subclass 23.4.

33. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 61 (encoding FL/Fc/her2Fv), classified in class 536, subclass 23.4.

34. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 63 (encoding hFLex/Trailex), classified in class 536, subclass 23.4.

35. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 65 (encoding hFLex/IZ/Trailex), classified in class 536, subclass 23.4.

36. Claims 24, 25 in part, 26-33, drawn to nucleic acids, antisense molecules, vectors, vector transfected cells, and methods of producing chimeric proteins with vector transfected cells of SEQ ID NO: 67 (encoding hFLex/Fc/Trailex), classified in class 536, subclass 23.4.

37. Claims 37-39, drawn to methods of treating a neoplasm comprising administering a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, classified in class 514, subclass 2 or class 530, subclass 387.3.

38. Claims 40 and 41, drawn to a combination comprising a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, and a neoplastic agent, classified in class 514, subclass 2 or class 530, subclass 387.3.

39. Claim 42, drawn to a methods of treating a neoplasm with a combination comprising a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, and a neoplastic agent, classified in class 514, subclass 2 or class 530, subclass 387.3.

40. Claims 43-46, drawn to methods of inducing caspace-3 mediated apoptosis in a cell comprising administering a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, classified in class 514, subclass 2 or class 530, subclass 387.3.

41. Claim 47, drawn to a vaccine comprising a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, and an immune response potentiator, classified in class 514, subclass 2 or class 530, subclass 387.3.

42. Claim 48, drawn to methods for eliciting an immune response comprising administering a vaccine comprising a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, and an immune response potentiator, classified in class 514, subclass 2 or class 530, subclass 387.3.

43. Claim 49, drawn to methods for producing a tumor-specific lymphocyte comprising administering a chimeric protein comprising an Flt3 ligand and a tumoricidal agent, classified in class 514, subclass 2 or class 530, subclass 387.3.

2. Claims 1-7, 19, 20, and 34-36 links inventions for Groups 1-43. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claim 1. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-132 (CCPA 1971). See also MPEP § 804.01.

3. The chimeric proteins of Groups 1-21, the polynucleotides of Groups 22-36, the combinations of Group 38 and the vaccines of Group 41 represent separate and distinct products, which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. (MPEP § 806.05(j)). In the instant case, the chimeric proteins of Groups 1-21 do not overlap the scope of the polynucleotides for Groups 22-36, the

combinations of Group 38 or the vaccines of Group 41, nor do the combinations of Group 38 or the vaccines of Group 41 overlap the scope of each other or that of the polynucleotides as evidenced by the distinct structures and functions of the claimed inventions.

A DNA's structure is comprised of linear, contiguous nucleotides, while a protein's structure is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein, while a protein's function, in the instant case, is to bind an Flt3 receptor while fused to a tumoricidal agent. Additionally, the DNA and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the DNA polypeptides have materially different functions as noted above.

With respect to each of the polypeptides of Groups 1-21, each represents an chimeric protein having a unique amino sequence with each sequence being translated from a unique mRNA. The chimeric proteins can also comprise different peptide linked domains being selected from the Ftl3 ligand of SEQ ID NO:2 or a tumoricidal agent comprising a specific antibody, Fas ligand, TNF or TRAIL and with the domains operatively linked in various combinations. Also, the chimeric proteins can occur in combinations with other agents such as anti-neoplastic agents (Group 38) or immune response potentiators (Group 41), which further modifies the activity or effect of the chimeric protein.

Additionally, each of the DNA/polynucleotides of Groups 22-36 encodes a separate and distinct fusion protein having a unique polynucleotide or DNA sequence

with domains or regions for each sequence being selected from the Ftl3 ligand or a tumoricidal agent comprising a specific antibody, Fas ligand, TNF or TRAIL.

Because these inventions are distinct for the reasons given above and the search required for Groups 1-21, 38 and 41 is not required for Groups 22-36, restriction for examination purposes as indicated is proper. While the Groups can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Groups 1-21, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the DNA sequences of Groups 22-36 must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups 1-36, 38 and 41 have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

4. The methods of Groups 37, 39, 40, 42 and 43 differ in the method objectives, method steps, intended populations, and in the reagents used. The methods of Groups 37, 39, 40, 42 and 43 differ as follows: Group 37 requires administering a chimeric protein of Ftl3 ligand and a tumoricidal agent to a mammal in a neoplasm-treating effective amount; Group 39 requires administering a chimeric protein of Ftl3 ligand and a tumoricidal agent in combination with an anti-neoplastic agent to a mammal in a neoplasm-treating effective amount; Group 40 requires administering a chimeric protein

of Ftl3 ligand and a tumoricidal agent to a cell in a caspase-3-mediated apoptosis inducing amount; Group 42 requires administering a chimeric protein of Ftl3 ligand and a tumoricidal agent with an immune response potentiator to a mammal in an anti-neoplasm immune response eliciting amount; and Group 43 requires administering a chimeric protein of Ftl3 ligand and a tumoricidal agent to a mammal in a tumor-specific lymphocyte producing amount in order to recover the tumor-specific lymphocyte. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus methods of Groups 37, 39, 40, 42 and 43 are separate and distinct in having different method steps, different endpoints, different intended populations and different reagents used, and thus are patentably distinct.

5. Inventions of Groups 1-21 and Group 37 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating a neoplasm in a mammal can be practiced with any number of therapies including radiation, antisense, gene therapy, chemotherapy, small molecule agonists or antagonists, etc. As for the fusion proteins, any one of them could be used in a materially different process such as for screening binding ligands, immunopurifying ligands, etc. The examination of all groups would require different searches in the U.S.

PATENT shoes and the scientific literature and would require the consideration of different patentability issues.

6. Inventions of Group 38 and Group 39 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

See the comments under section 5, supra, as they apply here.

7. Inventions of Group 1-21 and Group 40 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of inducing caspase-3-mediated apoptosis can be practiced with, for example, serine/threonine phosphatase inhibitors (Fladmark et al. (Cell Death Differ. 6:1099-108 (1999)). As for the fusion proteins, any one of them could be used in a materially different process such as for screening binding ligands, immunopurifying ligands, etc. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues.

8. Inventions of Group 41 and 42 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of eliciting an anti-neoplasm immune response (if required to be against the Ftl3 ligand) could be practiced with for example, an anti-Ftl3 ligand antibody. Otherwise, any anti-neoplasm immune response could be elicited by administering purified proteins or expression vector encoded proteins that are tumor specific in their expression. As for the vaccine, the components could be used for screening binding ligands, immunopurifying binding ligands, etc. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues.

9. Inventions of Groups 1-21 and Group 43 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the fusion proteins could be used for screening binding ligands, immunopurifying binding ligands, etc. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different searches in the patent literature, restriction for examination purposes as indicated is proper. To search Groups 1-41 together would also present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive. Thus, Groups 1-41 have been appropriately restricted on the basis of being both distinct and presenting a search burden on the Examiner if they were to be searched together.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

13. If Group 2 is elected, then species (antibody tumoricidal agent) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) anti-p230 antibody or a biologically active fragment thereof

Specie B) anti-CD29 antibody or a biologically active fragment thereof

Specie C) anti-Her2 antibody or a biologically active fragment thereof

Specie D) anti-Her3 antibody or a biologically active fragment thereof

Specie E) anti-Her4 antibody or a biologically active fragment thereof

Specie F) anti-EGFR antibody or a biologically active fragment thereof

The species of antibody A-F are each distinct. These antibodies are considered to be unrelated, since each of the antibodies is structurally and functionally independent and distinct for the following reasons: each antibody has a unique amino acid sequence, each antibody binds to a different antigen much less to a different epitope and each antibody has its own unique ability to stimulate an immune response and/or binding affinity to an antigen or epitope. Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the antibodies having obtained a separate status in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 16 is generic as to Species A-F.

14. If Group 37 is elected, then species (cancer) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) melanoma

Specie B) breast cancer

Specie C) hepatocellular carcinoma

The species A-C do not share a common utility nor do they have a substantial structural feature common amongst them. Each of the cancers of species A-C can originate from any number of different cell types (e.g., epithelial, endothelial or mesothelial). Also, the cancers being associated with different organs are nevertheless, under the influence of different growth factors and hormones. Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate cancers. Thus, species A-C are patentably distinct cancers. Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the cancers having obtained a separate status in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 39 is generic as to Species A-C.

15. If Group 38 is elected, then species (cancer for anti-neoplasm agent) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) melanoma

Specie B) breast cancer

Specie C) hepatocellular carcinoma

See the comments with respect to cancers as they pertain to these species under section 14, supra.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 41 is generic as to Species A-C.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

LAB